

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

IN RE AKARI THERAPEUTICS PLC
SECURITIES LITIGATION

17 Civ. 3577 (KPF)

CLASS ACTION

JURY TRIAL DEMANDED

**CONSOLIDATED AMENDED CLASS
ACTION COMPLAINT**

Lead Plaintiffs Dima Alghazzy and Shamcy Alghazzy (“Plaintiffs”), on behalf of all other persons similarly situated, allege the following based upon personal knowledge as to their own acts and upon information and belief as to all other matters based on the investigation conducted by Lead Counsel, which included a review of, *inter alia*, SEC filings by Akari Therapeutics, plc (“Akari” or the “Company”), press releases and other public statements by Defendants, media and analyst reports and advisories about Defendants and the Company, interviews with confidential witnesses, and other publicly available information. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased Akari publicly-traded securities listed on United States stock exchanges between April 24, 2017 and May 30, 2017, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder.

2. Akari is a small clinical-stage biopharmaceutical company focused on developing inhibitors of inflammation for the treatment of rare and orphan diseases. Akari has not commercialized any products or generated any revenue from the sale of products. Throughout the Class Period, Akari had only 15-16 full time employees.

3. Akari's leading product candidate is Coversin, a second-generation complement inhibitor. Coversin is core to the Company's operations.

4. Coversin shares a mechanism of action with a drug called Soliris (eculizumab), the only FDA-approved treatment for two ultra-rare autoimmune hemolytic disorders called paroxysmal nocturnal hemoglobinuria ("PNH") and atypical hemolytic uremic syndrome ("aHUS"). Soliris, made by Alexion Pharmaceuticals, Inc. ("Alexion"), is also one of the most expensive drugs in the world, with \$2.84 billion in sales in 2016.

5. Akari planned to seek FDA approval of Coversin as a first-line therapy for PNH and aHUS patients currently taking Soliris, as an alternative for Soliris-resistant PNH and aHUS patients, and also as a treatment for Guillain-Barré syndrome ("GBS") and certain other immune disorders with no currently-approved treatments.

6. Akari's drug development has been expensive. By December 31, 2016, Akari had accumulated a deficit of \$74.9 million. By June 30, 2017, the deficit had ballooned to \$87.8 million.

7. Akari relied on the sale of securities to fund operations and warned in its Annual Report for fiscal year 2016 that it would "require additional capital in order to develop and

commercialize our current product candidate There can be no assurance that additional funds will be available when we need them on terms that are acceptable to us...”¹

8. Akari also warned that its ability to raise capital would require an active market for its securities—which had yet to fully develop. As such, Akari explained that the “inactive market may also impair our ability to raise capital and may impair our ability to enter into strategic partnerships or acquire companies or products by using our ADSs or ordinary shares as consideration.”²

9. Thus, Akari was under pressure to ensure active trading and volume in the securities in order to raise much needed capital to continue with its operations.

10. On May 12, 2016, Akari announced that it received its first orphan drug designation from the FDA. Orphan drug designation is a special status conferred by the FDA to a drug or biological product intended to treat a rare disease or condition, and qualifies the sponsor of the drug for development incentives. This designation was a valuable opportunity for the Company, and a reason to seek out additional investment.

11. To that end, in approximately June 2016, Akari retained Edison Investment Research Ltd. (“Edison”) to deliver research reports on the Company to increase investor interest in Akari’s securities. Edison charges companies a flat annual rate in return for regular analyst coverage by its staff of sector specialists, in contrast to other research firms, who are paid by fund managers to access their content. This makes Edison’s business model similar to that of debt research companies such as Moody’s Investor Service and S&P Global Ratings, which have been plagued by issues of conflicts of interest.

¹ Form 20-F filed with SEC on March 31, 2017 at 3.

² *Id.*, at 15.

12. Edison, however, has defended its business model. In a March 19, 2017 interview with the Financial Times, Neal Shah, Edison's director of research, pointed out that Edison has turned down business from companies it had concerns about. Edison's Investment Research Principles, set forth on its website, state that "Our research brand strives to be objective, insightful, financially rigorous, readable and timely" and:

Our research must always reflect the informed view of our research analysts. In forming the informed view, our analysts strive to be diligent and thorough in their work, supporting their basis for opinions with appropriate levels of independent investigation, inquiry, analysis and judgement.

While Edison acknowledges that "[a]nalysts are permitted to fact check research drafts with the management of the subject company," analysts are supposed to report to Edison's director of research, not client management.

13. Edison issued its first report on Akari on June 20, 2016, as well as subsequent reports on July 8, 2016, January 9, 2017, and April 26, 2017. Each included disclaimer language stating:

This report has been commissioned by Akari Therapeutics and prepared and issued by Edison for publication globally. ***All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable,*** however we do not guarantee the accuracy or completeness of this report. ***Opinions contained in this report represent those of the research department of Edison at the time of publication.***

(Emphasis added.)

14. On March 30, 2017, Akari announced that Coversin had been granted "Fast Track" designation by the FDA for the treatment of PNH in certain patients with resistance to Soliris. The news prompted a sharp increase in the price and trading volume of Akari's American Depository Shares ("ADSs" or "shares"). After having hovered between \$6.50 and \$8 since the

beginning of 2017, Akari's share price doubled overnight on unprecedentedly high volume, jumping from \$6.98 on March 30, 2017 to close at \$11.07 on March 31, 2017. By April 10, 2017, it had reached \$19.70.

15. Against this backdrop, the Class Period begins on April 24, 2017, when the Company issued a press release entitled "Akari Therapeutics Demonstrates Positive Response with Coversin in Ongoing Phase 2 PNH Trial and in Additional Clinical Targets." That press release, however, was materially inaccurate, falsely stating that a patient who withdrew from the study (one of only five patients who participated in the trial) met the trial's primary endpoint before withdrawing, when that was not the case.

16. Two days later, on April 26, 2017, Edison issued a report titled "Akari's Coversin matches Soliris in Phase II" (the "Edison Report"). The Edison Report—which Defendant Dr. Gur-Arye Yehuda Roshwalb ("Roshwalb"), Akari's chief executive officer ("CEO"), had approved—significantly misrepresented Akari's data, overstating results and ignoring potential problems with the planned development process for Coversin.

17. On April 27, 2017, the Company announced that Edison had withdrawn the Edison Report, stating:

Edison Investment Research Ltd. has withdrawn its report issued yesterday titled "Akari's Coversin matches Soliris in Phase II" (the "Edison Report") ***because it contains material inaccuracies***, including without limitation, with respect to Akari's recently announced interim analysis of its ongoing Phase 2 PNH trial of Coversin. ***Investors should not rely upon any information contained in the Edison Report and instead should refer to Akari's press release issued on April 24, 2017 that discusses the interim analysis of its ongoing Phase 2 PNH trial and other matters.***

(Emphasis added.) Akari's April 24, 2017 press release, however, was itself materially inaccurate.

18. Then, on May 11, 2017, Akari announced that it had established an *ad hoc* special committee of the Board to review the involvement of Company personnel in preparing the inaccurate Edison Report—and that Roshwalb had been placed on administrative leave while the review was pending. On this news, the Company's share price fell \$2.46, or 21.41%, to close at \$9.03 on May 12, 2017.

19. On May 30, 2017, after market close, Akari issued a press release admitting to a false statement in its April 24, 2017 press release as well as false statements in connection with the Edison Report. Akari admitted that the April 24, 2017 press release had falsely stated that a patient who withdrew from the study met the trial's primary endpoint before withdrawing. It also announced that its special committee had determined that Roshwalb had contravened Company policy by reviewing and approving the Edison Report, which it had previously admitted contained material inaccuracies. Roshwalb was forced to resign as CEO.

20. On May 31, 2017, the Company's share price closed at \$6.13—down nearly 65% since April 24, 2017.

21. Throughout the Class Period, Defendants made materially false and misleading statements and omissions. Specifically, Akari and the Individual Defendants falsely stated that each of five patients in Akari's Phase IIb Coversin study met the study's primary endpoint, which was not true. The Defendants further failed to disclose that the Company's CEO had inappropriately reviewed and approved the Edison Report, in contravention of Company policy as well as Edison's research standards, using the Edison Report to publish false and misleading information. Because Coversin was extremely material and core to the Company's operations, Akari and the Individual Defendants were either aware of the true facts about Coversin when they made their false statements or recklessly turned a blind eye to the truth. Moreover, because

Akari was paying Edison, Edison had a conflict of interest that created a motive to make materially false statements concerning Akari.

22. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

23. The claims asserted herein arise under sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

24. This Court has subject matter jurisdiction under 28 U.S.C. §1331 and section 27 of the Exchange Act (15 U.S.C. § 78aa).

25. Venue is proper in this District under section 27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b), as the Company is headquartered in New York and the Company's ADSs trade on the NASDAQ.

26. In connection with the acts alleged herein, Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

27. Lead Plaintiffs Dima Alghazzy and Shamcy Alghazzy purchased Akari securities at artificially inflated prices during the Class Period and were damaged thereby.

28. Defendant Akari is headquartered in New York, with principal executive offices located at 24 West 40th Street, 8th Floor, New York, NY 10018. Before approximately June 2017, the Company was headquartered in the United Kingdom at 75/76 Wimpole Street, London W1G 9RT, United Kingdom. The Company's shares have traded on the NASDAQ Capital Market

under the symbol “AKTX” since September 21, 2015 and under the symbol “CLTX” from January 31, 2014 until September 18, 2015.

29. Defendant Roshwalb served as the Company’s CEO from March 2013 until his resignation on May 29, 2017. He also served as a director of Akari from June 2014 until his resignation on May 29, 2017.

30. Defendant Dov Elefant (“Elefant”) has served as the Company’s CFO since January 2012.

31. Defendant Ray Prudo (“Prudo”) has been the Company’s Executive Chairman since September 2015. He also served as acting CEO of Akari from May 11, 2017 to August 28, 2017.

32. Defendants Roshwalb, Elefant, and Prudo are referred to herein as the “Individual Defendants.”

33. Akari is liable for the acts of the Individual Defendants and its employees under the doctrine of respondeat superior, and common law principles of agency, as all of the wrongful acts complained of herein were carried out within the scope of their employment and with the authorization of Akari.

34. Defendant Edison is an investment research and advisory firm that charges companies for regular analyst coverage, generating reports that it then provides to fund managers. It has over 400 corporate clients.

35. Edison is liable for the acts of its employees under the doctrine of respondeat superior, and common law principles of agency, as all of the wrongful acts complained of herein were carried out within the scope of their employment and with the authorization of Edison.

SUBSTANTIVE ALLEGATIONS

Akari and Coversin

36. Akari was formed through a reverse merger between Celsus Therapeutics PLC (“Celsus”) and Volution Immuni Pharmaceuticals (“Volution”), which closed in September 2015.

37. Akari’s most promising venture is Coversin, a second-generation complement inhibitor. Complement inhibitors are used to treat certain rare autoimmune diseases affecting the complement system, a branch of the immune system that destroys and removes invading foreign pathogens. Coversin was derived from a protein originally discovered in the saliva of a species of tick. It was discovered in 2005 by Miles Nunn, who is now Akari’s Chief Scientific Officer.

38. Coversin uses the same mechanism of action as Soliris, the only currently approved treatment for PNH and aHUS. Soliris is one of the most expensive drugs in the world, generating \$2.84 billion in sales in 2016. This means that Coversin has both a proven clinical pathway for seeking regulatory approval as a treatment for PNH and aHUS and a proven market. Because Coversin can be administered more easily (subcutaneously by the patient) than Soliris (only intravenously by a healthcare professional), it could potentially compete with Soliris as a first-line therapy for PNH and aHUS, offer an alternative for Soliris-resistant patients, and possibly even treat other immune disorders for which Soliris is not effective.

39. On March 31, 2016, Akari announced preliminary results from the first PNH patient treated with subcutaneously administered Coversin. The patient, who was resistant to treatment with Soliris due to a polymorphism, was started on Coversin under a clinical trial protocol approved by an EU national regulatory authority. The patient demonstrated clinical and symptomatic improvement, complement inhibition, and a marked reduction of lactate dehydrogenase (“LDH,” a marker of blood hemolysis).

40. The summer of 2016 turned out to be an important one for the Company. On May 12, 2016, Akari announced that it received its first orphan drug designation in the United States when the FDA granted an orphan drug designation covering Coversin for GBS. Orphan drug designation is intended to encourage research and development of treatments for rare diseases, an orphan drug designation qualifies the sponsor of the drug for various development incentives, including tax credits for qualified clinical testing. These financial incentives now offer tremendous advantages to Akari in its development of Coversin.

Akari Retains Edison

41. After receiving its first orphan drug designation, Akari needed to raise capital to carry out Coversin clinical trials. To attract investor attention, in approximately June 2016, Akari retained Edison to publish research reports about the Company. Edison initiated coverage on June 20, 2016, publishing a report that valued the Company at \$273 million, or \$23.17 per ADS—almost twice the Company’s \$150 million valuation during the private placement carried out in connection with the reverse merger between Celsus and Volution, and significantly higher than its market cap at the time of \$172 million. Edison’s initial June 20, 2016 report also included a detailed, lengthy analysis of Coversin’s promise and prospects. In particular, Edison noted that the main clinical risks for Coversin were “safety related” and that Akari’s “current clinical strategy is to demonstrate superiority to Soliris in a head-to-head Phase III trial by demonstrating more complete control of symptoms.

42. Then, on July 6, 2016, Akari announced positive interim data from the first cohort in its Phase Ib Coversin trial. On July 8, 2016, Edison responded to Akari’s announcement by issuing a report increasing the Company’s valuation to \$376 million.

43. On September 12, 2016, Akari received another orphan drug designation from the FDA, this one covering Coversin for the treatment of PNH.

44. On January 9, 2017, Edison issued a report increasing Akari's valuation to \$398 million, largely based on "new data...on the unique profile of Coversin" suggesting that it had "a series of potential advantages over Soliris and potentially other complement inhibitors in development."

Fast Track Designation Raises Akari's Profile and Share Price

45. On March 30, 2017, the Company announced in a press release that the FDA had "granted Fast Track designation for Coversin™ for treatment of paroxysmal nocturnal hemoglobinuria (PNH) in patients who have polymorphisms conferring eculizumab resistance." Fast Track is one of several FDA programs designed to facilitate and expedite the development and review of new drugs to address unmet medical needs in the treatment of serious conditions, and drugs that receive Fast Track designation are eligible for various benefits that often lead to earlier FDA approval.

46. The news prompted a sharp increase in Akari's share price and trading volume. After having hovered between \$6.50 and \$8 since the beginning of 2017, Akari's share price doubled overnight on unprecedentedly high volume, jumping from \$6.98 on March 30, 2017 to close at \$11.07 on March 31, 2017. By April 10, 2017, it had reached \$19.70.

Materially False and Misleading Statement: The April 24, 2017 Press Release

47. On April 24, 2017, Akari issued a press release entitled "Akari Therapeutics Demonstrates Positive Response with Coversin in Ongoing Phase 2 PNH Trial and in Additional Clinical Targets." The release reported interim data from a 90 day, open label trial of five patients with PNH who had not received prior anti-complement therapy, who were treated with Coversin. Akari stated that all five patients had reached the study's primary endpoint of reduction in serum LDH to ≤ 1.8 times the upper level of normal ("ULN") or 500 units per liter ("U/L"), whichever was the lower from day 1 (pre-dose) to day 28. It noted that one of the five

(“Patient 5”) achieved the primary endpoint at day 14, but was withdrawn from the trial at day 43, and that Patient 5’s clinical response fluctuated and did not stabilize. According to the release, the other four patients experienced LDH reductions to 1.3, 1.4, 1.5 and 1.8 times ULN. Akari further stated that it was planning to initiate Phase III trials for PNH patients in the fourth quarter of 2017.

48. The April 24, 2017 Press Release was false and misleading because it claimed that Patient 5, who withdrew from the trial, met the primary endpoint. As Akari later admitted on May 30, 2017, this was not true. Especially in a study that included only five patients (four or whom completed the treatment protocol), mischaracterizing a patient as meeting the primary endpoint materially misrepresented the clinical data.

Materially False and Misleading Statement: the April 26, 2017 Edison Report

49. On April 26, 2017, Edison issued a report titled “Coversin matches Soliris in Phase II.” The headline alone was materially misleading. Claiming that Coversin “matche[d] Soliris in Phase II” ignores the significant differences between Akari’s Phase II trial and Alexion’s Soliris research. Akari’s Phase II trial treated and studied five PNH patients (one of whom dropped out of the trial). Alexion’s initial trial for Soliris was more than twice as large, treating and studying 11 PNH patients.³ Furthermore, Alexion achieved better results. Its data showed that Soliris cut LDH levels in patients from 2,032 units per liter (U/L) to 239 U/L in 26 weeks, while Akari chose 500 U/L as its primary endpoint. While figures for the ULN of LDH for Soliris patients vary from source to source, 223 U/L translates into a drop in LDH from 9.1

³ See Hillmen P, Muus P, Duhrsen U, et al. Effect of the complement inhibitor eculizumab on thromboembolism in patients with paroxysmal nocturnal hemoglobinuria. *Blood*. 2007;110(12):4123-4128. doi:10.1182/blood-2007-06-095646. Alexion ultimately tested Soliris on 195 patients with PNH.

times ULN to 1.1 times ULN, which is substantially lower than the 1.8 times ULN primary endpoint in Akari's study. Moreover, Akari's patients started at lower LDH levels. While patients in the Soliris study experienced a drop in LDH from 9.1 times ULN to 1.1 times ULN, according to Akari's April 24, 2017 press release, the five patients in the trial started at 2.4 times ULN, 7.5 times ULN, 3.3 times ULN, 5.6 times ULN, and 3.7 times ULN.⁴

50. The Edison Report further mischaracterized the effect of Coversin relative to Soliris by stating that "[t]he four patients who completed the study met the primary endpoint of hemolysis within 1.8x the upper limit of normal (ULN), with the average at 1.5x ULN, ***which is considered optimal control similar to Soliris.***" (Emphasis added.) Indeed, the Edison report repeatedly described 1.5 times ULN as similar to the outcome of Soliris trials. The Edison Report did not, however, explain who, exactly, considered 1.5 times ULN to be optimal control similar to Soliris, or why that number was chosen as the primary endpoint in Akari's study. It also did not disclose that Soliris patients actually achieved lower LDH levels, after starting at higher baseline levels.

51. The Edison Report was also misleading because it characterized Coversin as achieving the "[s]ame results as Soliris" (and even "comparable to results seen during the clinical trials of Soliris") even though Akari did not carry out a head-to-head trial between the two drugs. Under FDA regulations, "statements comparing the safety or effectiveness of the drug with other agents for the same indication must ... be supported by substantial evidence derived from adequate and well-controlled studies..." 21 C.F.R. § 201.57(c)(2)(iii). The FDA has further

⁴ See Nick Paul Taylor, *Akari puts CEO on administrative leave pending probe of inaccurate analyst report, sinking stock*, FIERCEBIOTECH (May 12, 2017), <http://www.fiercebiotech.com/biotech/akari-puts-ceo-administrative-leave-pending-probe-inaccurate-analyst-report-sinking-stock>.

explained that “[f]or claims of similar effectiveness, such evidence would include adequate and well-controlled trials designed to demonstrate that one treatment is not inferior to another and that the difference between the two is not clinically significant.” However, comparing the average rate of hemolysis from a Coversin study with data from a Soliris study does not prove that Coversin generates the same results as Soliris; it is not possible to compare one drug to another without comparing them in the same study. This would be true even if the Coversin study had shown similar drops from similar baseline LDH numbers, which it did not.

52. The Edison Report additionally mischaracterized Akari’s plans for Phase II trials. The Edison Report stated that Akari was planning two Phase III clinical trials. It described one, CAPSTONE, as “a randomized, placebo-controlled trial for newly diagnosed PNH patients compared to placebo and standard of care” and the second, ASSET, as “a head-to-head, open-label comparison study between Coversin and Soliris.” Both descriptions were materially misleading.

53. CAPSTONE, which the Edison Report described as a trial comparing Coversin treatment to “standard of care,” will test Coversin as an *additional treatment to transfusion*. Transfusion is only the standard of care treatment in countries where Soliris is not the standard of care. Soliris is the standard of care for PNH in the United States. The Edison Report misled investors by failing to precisely describe what “standard of care” CAPSTONE would test Coversin against.

54. ASSET, which the Edison Report describes as a “head-to-head, open-label comparison study between Coversin and Soliris,” is actually a randomized, head-to-head, two arm, open-label, non-inferiority study in which patients already being treated with Soliris will be randomized to either continue on Soliris or switch onto Coversin. It does not examine the effect

of Coversin on patients who have not already received Soliris treatment, and will not provide data on the effectiveness of Coversin as a first-line treatment for PNH.

55. Neither Akari nor Edison disclosed that Defendant Roshwalb reviewed and approved the Edison Report, including approving its numerous material misrepresentations concerning Akari's Phase II Coversin study and its plans for the Phase III CAPSTONE and ASSET studies.

Akari and Edison Make a Series of Partial Corrective Disclosures

56. On April 27, 2017, Edison withdrew the Edison Report. The Company issued the following statement:

Edison Investment Research Ltd. has withdrawn its report issued yesterday titled "Akari's Coversin matches Soliris in Phase II" (the "Edison Report") because it contains *material inaccuracies, including without limitation, with respect to Akari's recently announced interim analysis of its ongoing Phase 2 PNH trial of Coversin*. Investors should not rely upon any information contained in the Edison Report and instead should refer to Akari's press release issued on April 24, 2017 that discusses the interim analysis of its ongoing Phase 2 PNH trial and other matters.

57. That same day, Edison also suspended its coverage of Akari, issuing the following statement:

Whilst following Edison's normal publication process, which includes a review of a note by a supervisory analyst and a fact checking of the document by the issuer, it has come to light that there were material errors in the last note Edison published on Akari Therapeutics. Edison has withdrawn the last note from circulation and is conducting a review of the coverage. Whilst we undertake this review, the Director of Research has taken the decision to suspend coverage of Akari Therapeutics. Accordingly, our current investment views and earnings estimates for the stock are no longer in effect and should not be relied upon by investors.

58. Edison's statement failed to disclose Roshwalb's role in reviewing and approving the Edison Report. In the disclaimer that appeared on each report issued by Edison about Akari,

Edison stated “This report has been commissioned by Akari Therapeutics and prepared and *issued by Edison* for publication.” In other words, Edison continued to falsely assert that Edison fact checked its own reports.

59. On May 11, 2017, the Company announced that its Board of Directors had “established an *ad hoc* special committee of the Board to review the involvement, if any, of Company personnel with the Edison Report.” The Company also disclosed that Defendant Roshwalb, the Company’s CEO, had been placed on administrative leave pending the review and that Defendant Prudo, the Company’s Executive Chairman, had temporarily assumed Roshwalb’s duties in his absence.

60. On the news that Roshwalb was being suspended in connection with an investigation into the participation of Akari personnel in the issuance of Edison’s misleading April 26, 2017 report, the Company’s share price fell \$2.46, or 21.41%, to close at \$9.03 on May 12, 2017.

61. The next day, on May 12, 2017, Edison responded by issuing the following statement both defending the contents of the Edison Report and finally admitting the role of Akari management in approving the content of its analyst reports:

Edison Investment Research Inc. (“Edison”), an investment research and advisory company, wishes to comment on statements made by Akari Therapeutics (“Akari”) in its press release dated April 27, 2017 and the SEC filing dated May 11, 2017.

Edison’s analysts follow a strict and extensive review process prior to the publication of any report, including the April 26, 2017 note on Akari (the “Note”). Edison’s analyst team carried out the Edison Process, including engaging the client, Akari, to review and provide feedback on the report and notify us if any inaccuracies or misrepresentations appeared in the final draft of the Note. *Following a review of the report by Akari’s senior management, Edison was provided with specific written approval for the publication of the Note as published.*

Following the publication of the Note on April 26, 2017, Akari management contacted Edison to notify that “certain errors” were found in the Note without providing Edison with further explanation regarding the alleged errors. *Akari management subsequently requested Edison retract the Note and announced “material inaccuracies” were found in the Note.*

Despite an in-depth investigation, *Edison has yet to find any evidence of inaccuracies nor have details of any alleged inaccuracies been provided by Akari representatives, despite multiple requests from Edison* and by Edison’s legal counsel, Barton LLP, to Edison’s legal counsel. Edison believes the published Note consistently reflected the accuracy of the information contained in and written by Akari in Akari’s press release dated April 24, 2017.

62. A May 12, 2017 article in *FierceBiotech*⁵ explained why the Edison Report was misleading:

The note published by Edison said Coversin achieved the ‘same results’ as Alexion’s Soliris, the only drug approved to treat paroxysmal nocturnal hemoglobinuria (PNH), from a once-daily injection. It is questionable whether the data support this conclusion.

In the phase 2 trial, Akari gave Coversin to five patients with PNH. Among the four patients who stayed on the drug, levels of lactate dehydrogenase (LDH) were between 2.4 and 7.5 times the upper limit of normal (ULN) at baseline. LDH levels fell to between 1.3 and 1.8 times the ULN during the course of the 90 day study.

The Edison report claimed the data amounted to Coversin matching Alexion’s drug. Soliris won approval in the indication in 2007 on the strength of data showing it cut LDH levels from 2,032 units per liter (U/L) to 239 U/L in 26 weeks. Figures for the ULN of LDH vary from source to source. But using the 223 U/L cited in research by Alexion, the data translate into an eculizumab-driven drop in LDH from 9.1 times ULN to 1.1 times ULN.

⁵ Nick Paul Taylor, *Akari puts CEO on administrative leave pending probe of inaccurate analyst report, sinking stock*, FIERCEBIOTECH (May 12, 2017), <http://www.fiercebiotech.com/biotech/akari-puts-ceo-administrative-leave-pending-probe-inaccurate-analyst-report-sinking-stock>. *FierceBiotech*, which covers the biotechnology industry, is the most actively read daily publication in the life sciences.

Edison's report put the ULN figures for two Soliris trials at 9.9 times at baseline and 1.5 and 1.3 times post treatment. The comparability of the post-treatment ULNs from the Coversin and Soliris trials appears to underpin Edison's conclusion about the significance of the data, despite the major differences in the size of the studies and baseline characteristics of the patients.

63. On May 30, 2017, the Company announced that Roshwalb had resigned as CEO in connection with the investigation into Akari employees' role in the Edison Report, stating in a press release:

As previously reported by the Company, its Board of Directors established an *ad hoc* special committee of the Board to review the involvement, if any, of Company personnel with the report issued by Edison Investment Research Ltd. ("Edison") on April 26, 2017 titled "Akari's Coversin matches Soliris in Phase II" (the "Edison Report"), which was later retracted. Edison was retained by the Company to produce research reports about the Company. While that review was pending, Dr. Gur Roshwalb, the Company's Chief Executive Officer, was placed on administrative leave and Dr. Ray Prudo in his role as Executive Chairman temporarily assumed Dr. Roshwalb's duties in his absence.

Following that review, the Company determined that the Edison Report was reviewed and approved by Dr. Roshwalb, in contravention of Company policy. On May 29, 2017, Dr. Roshwalb submitted his resignation as Chief Executive Officer and member of the Company's Board of Directors, effective immediately. The Company has commenced an executive search to identify a replacement Chief Executive Officer and in the interim, Dr. Ray Prudo will continue to act as the Company's Chief Executive Officer.

64. In other words, Roshwalb—who, as CEO had the authority to bind Akari, which in turn exercised control over Edison in connection with its Akari coverage—was responsible for the release of a misleading report that misrepresented Akari's Phase II Coversin study. He was forced to resign as a result of this misconduct.

65. The Company also admitted additional fraud. In the same May 30, 2017 press release, the Company announced that the Company's April 24, 2017 press release—which Akari

had instructed investors to rely on as recently as April 27, 2017, when it disavowed the Edison Report—was *inaccurate itself*:

In addition, the Company has determined following that review that the previously reported interim analysis of the Company's ongoing Phase 2 PNH trial of Coversin (the "Interim Phase 2 Results"), as stated in the Release, was *inaccurate with respect to one of five patients* for whom information was provided in the Release. *The Release stated that the "fifth patient with an LDH of 3.7 X ULN at baseline achieved the primary endpoint* at day 14, but was withdrawn from the trial at day 43 due to a suspected co-morbidity unrelated to treatment, which would have excluded the patient from the trial protocol. While on Coversin, the patient met the primary endpoint (day 14), and achieved and maintained a CH50 <LLQ (day 1) but clinical response fluctuated and did not stabilize. After withdrawal, the patient switched to eculizumab. On eculizumab, LDH decreased to below 1.5X ULN and the patient experienced other clinical complications." *The Company has found that the fifth patient*, who was withdrawn from the trial at day 43 due to a suspected co-morbidity unrelated to treatment, *did not meet the primary endpoint*.

66. A May 31, 2017 article in *FierceBiotech*⁶ described the fallout from Akari's attempt to misdirect investors about its Phase II data as follows:

The CEO of Akari Therapeutics has quit amid a probe into the release of phase 2 data and a related analyst report. An investigative committee ruled that ex-CEO Gur Roshwalb, M.D., had contravened company policy and found an Akari statement falsely claimed a patient met the primary endpoint in a phase 2 trial.

Akari convened the ad hoc committee in response to the publication and subsequent withdrawal of a report by Edison Investment Research. Edison drafted a report for Akari to describe data from a phase 2 trial of Coversin, the biotech's rival to Alexion's Soliris. The committee found Roshwalb reviewed and approved the Edison report. One day after publication, Edison pulled the report after learning it contained "material errors."

⁶ Nick Paul Taylor, *Akari CEO quits after probe uncovers dodgy data release*, FIERCEBIOTECH (May 31, 2017), <http://www.fiercebiotech.com/biotech/akari-ceo-quits-after-probe-uncovers-dodgy-data-release>.

At that time, Akari pointed investors to its own press release for an accurate write up of the data. But it has now emerged that the errors extend beyond the Edison report. Akari's latest statement flags up a false claim in its own press release to unveil the phase 2 data. That release claimed one of the five patients met the primary endpoint before withdrawing from the study. The committee found the patient did not meet the primary endpoint.

Akari focused its positive spinning of the data on the four patients who remained in the study, not the fifth who withdrew. Yet, while that dampens the significance of the error on the prospects of Coversin, the inability of Akari to accurately report results from a five-patient study reflects badly on the company. It has also contributed to Akari lacking a permanent leader and facing lawsuits at a time when it should be fully focused on advancing Coversin into phase 3.

Class Action Allegations

67. Plaintiffs bring this action as a class action under Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than Defendants who purchased Akari publicly-traded securities listed on United States stock exchanges during the Class Period (the "Class"). Excluded from the Class are Defendants and their immediate families, the officers and directors of the Company and Edison at all relevant times, their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

68. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's shares was actively traded on the Exchange. While the exact number of Class members can only be ascertained through discovery, Plaintiffs believe that there are at least hundreds of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company and/or its transfer agent.

69. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct.

70. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

71. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a) whether Defendants violated the federal securities laws;
- b) whether statements made by Defendants misrepresented material facts about the Company's business, management, and operations;
- c) whether the Individual Defendants caused the Company to issue false and misleading statements during the Class Period;
- d) whether Defendants acted knowingly or recklessly in issuing materially false and misleading statements;
- e) whether Defendants' conduct caused artificial inflation in the price of the Company's securities; and
- f) whether the members of the Class have sustained damages, and if so, the proper measure of such damages.

72. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually

redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

73. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- a) Defendants made public misrepresentations or failed to disclose facts during the Class Period;
- b) The Company's securities traded on the Exchange and in an efficient market;
- c) The Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- d) The misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- e) Plaintiffs and other members of the Class purchased the Company's securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

74. At all relevant times, the market for the Company's securities was open, well-developed, and efficient for the following reasons, among others:

- a) The Company's securities traded on the Exchange;
- b) As a regulated issuer, the Company filed periodic public reports with the SEC; and
- c) The Company regularly communicated with public investors via established market communication mechanisms, including through regular

dissemination of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services.

75. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

76. Alternatively, Plaintiffs and the members of the Class are entitled to a presumption of reliance under *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Against Akari and the Individual Defendants for Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 in Connection with Akari's Statements During the Class Period and Against Edison, Akari, and Roshwalb for Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 in Connection with the Edison Report)

77. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

78. During the Class Period, each of the Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including

Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Akari securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Akari securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

79. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the statements described above. Such releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Akari's operations.

80. By virtue of their positions, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

81. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Akari, the Individual Defendants had knowledge of the details of Akari's internal affairs.

82. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Akari as well as Edison, which they retained to provide coverage of Akari. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Akari's business, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Akari securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Akari's business and financial condition which were concealed by defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Akari securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by defendants, and were damaged thereby.

83. Edison is additionally liable for the material false statements in the Edison Report because it misled investors and allowed Roshwalb to influence its public statements about Akari without regard for the statements' accuracy.

84. During the Class Period, Akari securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Akari securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated

prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Akari securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Akari securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

85. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

86. As a direct and proximate result of defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company and Edison had disseminated materially false statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

87. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

88. During the Class Period, the Individual Defendants participated in the operation and management of Akari, and conducted and participated, directly and indirectly, in the conduct of Akari's business affairs. Because of their senior positions, they knew that Akari made false statements about its Phase II Coversin trial, both through statements made by the Company during the Class Period and through the Edison Report on April 26, 2017.

89. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information concerning Akari, and to

correct promptly any public statements issued by Akari which had become materially false or misleading.

90. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Akari disseminated in the marketplace during the Class Period concerning Akari's clinical study results. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Akari to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Akari within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Akari securities.

91. Each of the Individual Defendants, therefore, acted as a controlling person of Akari. By reason of their senior management positions and/or being directors of Akari, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Akari to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Akari and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

92. In addition, Akari and Roshwalb acted as controlling persons of Edison in connection with Edison's reports about Akari. By providing false content for Edison to publish and retaining final approval power over Edison's reports, Roshwalb had the power to direct Edison to engage in the unlawful acts and conduct complained of herein, which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

93. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Akari.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Federal Rule of Civil Procedure 23, and certifying Plaintiffs as Class representatives and Plaintiffs' counsel as Class Counsel;

B. Awarding compensatory damages in favor of Plaintiffs and the Class against all Defendants, jointly and severally, for damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial;

C. Awarding Plaintiffs and the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: November 6, 2017

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

/s/ Phillip Kim
Phillip Kim, Esq. (PK 9384)
Laurence M. Rosen, Esq. (LR 5733)
275 Madison Avenue, 34th Floor
New York, New York 10016
Telephone: (212) 686-1060
Fax: (212) 202-3827
Email: pkim@rosenlegal.com
Email: lrosen@rosenlegal.com

and

Leah Heifetz (LH 0402)

101 Greenwood Avenue, Suite 440
Jenkintown, PA 19046
Telephone: (215) 600-2817
Fax: (212) 202-3827
Email: lheifetz@rosenlegal.com

POMERANTZ LLP

Jeremy Lieberman
Murielle Steven Walsh
Aatif Iqbal
600 Third Avenue, 20th Floor
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
Email: jalieberman@pomlaw.com
mjsteven@pomlaw.com
aiqbal@pomlaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on November 6, 2017, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send notification of such to all CM/ECF participants.

Dated: November 6, 2017

/s/ Leah Heifetz

Leah Heifetz